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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,058

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EXAMINER

STUART, COLIN W

ART UNIT

PAPER NUMBER

4177

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,058	<b>Applicant(s)</b> GRUNDLER ET AL.	
	<b>Examiner</b> COLIN STUART	<b>Art Unit</b> 4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "humidification is comprised sprinkling" (Claim 8 ln. 7) is unclear in its scope. The examiner is reading this phrase to limit the humidification chamber to a sprinkling type.

Regarding claim 10, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-2, 4-5, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (4,541,966).**

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As to claim 1, Smith teaches a gas humidifying apparatus that humidifies gas flowing "to the lungs of a patient in an artificial ventilation system" (col. 1 ln. 7). The device taught is a "humidifier in the form of a nebulizer 8" (col. 4 ln. 39; Fig. 1). Fig. 2 shows the nebulizer which "comprises a chamber 11 having a gas inlet 12 in the form of a cannula and an outlet 13" (col. 4 ln. 50). This chamber (11) is the humidification chamber with gas inlet and outlet as claimed. Also, in connection with the chamber is a "small reservoir 15 having a liquid inlet 16" (col. 4 ln. 54) as seen in Fig. 2. The nebulizer also includes "an electric heating element (not shown)" (col. 5 ln. 14) which functions to assure "the gas supplied to the patient is suitably warm" (col. 5 ln. 16). Smith teaches "a pump 20" (col. 5 ln. 23) which supplies liquid to the reservoir (15) and a valve (5) which when open, "the gas pressure within the chamber 11 rises" (col. 5 ln. 1) and "causes liquid to be forced up the tube 18" (col. 5 ln. 4) and "entrained and nebulized by the rapidly moving gas flow" (col. 5 ln. 8). The pump (20) and the valve (5) are the drive device as it functions to move fluid through the gas as claimed.

As to claim 2, the "sprinkling type chamber" (Claim 2 ln. 2) as defined by the applicant is "such a chamber [that] the fluid is moved through the gas" (Para 0052). In light of the applicant's disclosure, the humidification chamber as taught by Smith is a sprinkling type chamber as claimed, because as the "pressure within the chamber 11 rises" (col. 5 ln. 1) it causes "liquid to be forced up the tube 18" (col. 5 ln. 4) from the reservoir and "is entrained and nebulized by the rapidly moving gas flow" (col. 5 ln. 8).

As to claim 4, the humidification chamber taught by Smith is pressurized as claimed because the valve (5) functions to raise "the gas pressure within the chamber 11" (col. 5 ln. 1).

As to claim 5, Smith teaches a pump (20) which functions to supply fluid from another "liquid source" (col. 5 ln. 24) to the reservoir (15) and, with the help of a pressure differential caused by the valve (5), moves the fluid into the humidification chamber (11). The outside "liquid source" (col. 5 ln. 24), the pump, the reservoir, and the chamber are all connected in circuit as claimed "via a line 21" (col. 5 ln. 23), "liquid inlet 16" (col. 4 ln. 55), and "via a narrow tube 18" (col. 4 ln. 57) respectively.

As to claim 8, Smith teaches a method for using the gas humidifying apparatus which starts with "an inlet 1 which is connected in use to a compressed medical gas supply" (col. 4 ln. 6). Smith's method controls the generation of gas flow to the patient through a "valve 5 [that] produces gas pulses" (col. 4 ln. 30). From here the "pulsed gas flow passes through a humidifier" (col. 4 ln. 38) where the liquid is "entrained and nebulized by the rapidly moving gas flow" (col. 5 ln. 8) and the "gas supplied to the patient is appropriately warmed" (col. 3 ln. 42). After the gas flow passes the humidifier, it is "supplied directly to the lungs of a patient" (col. 4 ln. 40). As discussed above, the humidification chamber (11) of Smith is the sprinkling type as claimed by the applicant.

As to claim 9, the "valve 5 [which] produces gas pulses" taught by Smith is before the humidification chamber where the heating and humidification of the gas pulse takes place seen by Fig. 1.

As to claim 10, as discussed above, the humidification chamber taught by Smith is pressurized as claimed because the valve (5) functions to raise "the gas pressure within the chamber 11" (col. 5 ln. 1). The gas within the humidification chamber (11) inherently has a temperature higher than the gas flowing into the patient because of heat losses, which is a fundamental heat transfer principle, occurring at the "flexible tubing 10" (col. 4 ln. 42) which has no heating element to prevent losses. Once the gas passes through the humidification chamber, the "pressure in the tube 10 upstream of the jet 9 may be in the order of 100-200 kPa" (col. 4 ln. 45) which is a range containing normal respiratory gas pressure and within the 0.1 bar above ambient air pressure (1 bar or 101.325 kPa). Smith teaches that his apparatus assures "the gas supplied to the patient is suitably warmed" (col. 5 ln. 16) and humidified for use in ventilation respiratory systems which inherently require the gas to be at body temperature (37 C) and almost full saturation (100% humidity) as claimed.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (4,541,966) as applied to claim 1 above, and further in view of Anthony (5,172,686).**

As to claim 3, Smith teaches all the limitations of claim 1 as discussed above; however, Smith is silent as to providing the humidification chamber with filling material. Anthony teaches "a device for supplying air or medical gases in a conditioned, particularly a moistened and/or heated state to a patient" (Abstract). Anthony teaches a chamber (7) seen in Fig. 1 and 2 which is "filled with a material which may be provided in the shape of fibers or beads, as indicated by numeral 10" (col. 2 ln. 50). This filling material taught by Anthony "adsorbs water on the surface ... while still letting air through unhindered" (col. 2 ln. 53) as required by the applicant's disclosure of the filling material. The filling material (10) in the chamber (7) taught by Anthony forms a surface inside the chamber (7). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the humidification chamber of Smith to include filling material in view Anthony, because Anthony states that the filling material (10) acts to "insure optimum moistening" of the gas. (col. 2 ln. 48).

**8. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (4,541,966) as applied to claim 1 above, and further in view of Hitzler (4,829,781).**

As to claim 6, Smith teaches all the limitations of claim 1 as discussed above; however, Smith is silent as to using a rotating body which dips into the fluid to humidify the gas. Hitzler teaches an air humidifying device in which "a plate stack (13) partially dipping into the liquid rotates" (col. 4 ln. 15; Fig. 1). The rotating plate stack (13) of Hitzler is the rotating body drive device as claimed. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the humidification chamber of Smith to combine the fluid reservoir (15) within the chamber and to use a rotating plate stack (13) in view of Hitzler to humidify the gas, because Hitzler states that "the slowly rotating disks of the plate stack are constantly wetted, so that both air purification by adsorption and air humidification can take place" (col. 1 ln. 21).

As to claim 7, the rotating body taught by Anthony discussed in the paragraph above is a plate stack comprising multiple rotating disks. The plates in the stack are connected to each other with a distance as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. S./  
Examiner, Art Unit 4177

/Michael C. Astorino/  
Primary Examiner, Art Unit 3769

December 29, 2008